

**REMARKS**

Claims 16 and 17 are all the claims pending in the application.

Claims 16 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fumio [Kito] et al (JP Abstract 04-243825 hereinafter “Fumio”), in view of Omori (JP Abstract 04-149426A).

The Examiner states that Fumio discloses oral administration of tranexamic acid and ascorbic acid capable of curing pigmentation. The Examiner further states that Fumio does not disclose the use of L-cysteine. To remedy this deficiency, the Examiner relies on Omori as disclosing a solid pharmaceutical preparation comprising L-cysteine, which is said to have effects on alleviation of dermal stains.

It is the Examiner’s position that it would have been obvious for one of ordinary skill in the art to incorporate L-cysteine of Omori into the composition of Fumio since both references are attempting to solve the same problem of skin bleaching by oral administration.

Applicants traverse the rejection as improper.

Applicants submit that Omori et al (JP 04-149426) is not prior art to the present application. Omori et al was published on May 27, 2004, which is after the effective U.S. filing date of the present application of December 26, 2003 based on the filing date of the international application. Therefore, Omori et al can not be a prior art reference to the present application and the rejection is improper.

Further, Applicants submit that the primary reference, Fumio does not disclose, teach or suggest all elements of the claimed invention. Specifically, Fumio does not specifically disclose,

teach or suggest “a combination of tranexamic acid and L-cysteine” and “a combination of tranexamic acid, L-cysteine, and ascorbic acid” according to the present invention.

Fumio, JP ‘825, corresponds to CA 2086565, which was cited in the Information Disclosure Statement filed June 27, 2005, and which is referred to herein as an English equivalent. Fumio is directed to a combination of tranexamic acid and ascorbic acid for internal use in the treatment of pigmentation. The “Background of the Invention” section of Fumio states, “Conventionally, proposed treatment for pigmentation includes drugs for external use containing hydroquinone, vitamin C derivatives, kojic acid, tranexamic acid, etc. and drugs for internal use containing vitamin C, L-cysteine, glutathione, tranexemic acid, etc.” However, Fumio teaches away from the use of these drugs except for hydroquinone in stating that none of these drugs except hydroquinone preparations shows a sufficient effect in a short time. Therefore, one of ordinary skill in the art would not have been motivated to add L-cysteine or any of the other drugs mentioned in the “Background of the Invention” section to the composition of Fumio. Specifically, in view of the teaching of Fumio that L-cysteine is one of the drugs that was not shown to have a sufficient effect, one of ordinary skill in the art would not have been motivated to specifically add L-cysteine to the combination of tranexamic acid and ascorbic acid taught by Fumio or to substitute L-cysteine for ascorbic acid in the composition of Fumio. For at least this reason, the present invention is not rendered obvious by Fumio.

Even further, the present invention provides unexpectedly superior effects as previously mentioned. As is clear from the test examples in the specification (Table 1 on page 13), the combination of tranexamic acid and L-cysteine (sample 6) and the combination of tranexamic acid, L-cysteine and ascorbic acid (sample 8) show extremely excellent effect to prevent pigmentation in comparison with the combination of tranexamic acid and L-ascorbic acid

(sample 5). On the other hand, since the result of the combination of L-cysteine and ascorbic acid (sample 7) was not excellent, one skilled in the art would not have reasonably expected a composition in which a plural number of compounds are combined, each having an effect to prevent pigmentation, to show an excellent effect to prevent pigmentation. For this additional reason, the present invention is patentable over the cited art.


In view of the above, the method of whitening according to the present invention, which is characterized in that “a combination tranexamic acid and L-cysteine” or “a combination of tranexamic acid, L-cysteine and ascorbic acid” is administered, is not obvious to one skilled in the art.

Accordingly, Applicants respectfully request withdrawal of the §103 obviousness rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

  
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